

Federal Court



Cour fédérale

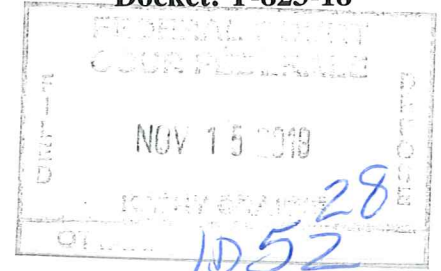
Date: 20181115

Docket: T-823-18

Ottawa, Ontario, November 15, 2018

PRESENT: Case Management Judge Mandy Ayles

BETWEEN:



HOFFMANN-LA ROCHE LIMITED, BIOGEN  
INC., GENENTECH, INC., AND F.  
HOFFMANN-LA ROCHE LIMITED

Plaintiffs/  
Defendants by Counterclaim

and

SANDOZ CANADA INC.

Defendant/  
Plaintiff by Counterclaim

**ORDER**

(Identical to Confidential Order dated November 5, 2018)

[1] The Defendant and Plaintiff by Counterclaim, Sandoz Canada Inc. [Sandoz], has brought a motion in this action and related actions T-824-18, T-825-18 and T-826-18, seeking:

- A. An order pursuant to Rule 221 of the *Federal Courts Rules* [Rules] striking out the Statements of Claim in T-823-18, T-824-18, T-825-18 and/or T-826-18;

- B. In the alternative, an order pursuant to Rule 221 of the *Rules* striking out of each Statement of Claim and Reply and Defence to Counterclaim the paragraphs set out in Schedules A and B to the Notice of Motion (or any of them);
- C. In the further alternative, an order pursuant to Rule 181(2) of the *Rules* ordering the Plaintiffs to serve and file further and better particulars in respect of the allegations listed at Schedule B to the Notice of Motion within 21 days of the date of the Court's order on the motion, failing which their pleadings will be struck;
- D. Costs of the motion; and
- E. Such further or other relief as counsel may advise and as to this Honourable Court may deem just.

[2] As part of its responding motion materials, the Plaintiffs included a proposed Amended Statement of Claim and Reply and Defence to Counterclaim for each action. On October 9, 2018, Sandoz: (a) advised the Court that the parties agreed to narrow the issues on the motion; (b) advised the Court that the motion would be argued on the basis of the Plaintiffs' proposed amended pleadings; and (c) provided the Court with a revised Schedules A and B, which narrowed the portions of the pleadings sought to be struck and the particulars requested. Accordingly, I have determined the motions based on the revised Schedules A and B.

Analysis

[3] The threshold for striking out a statement of claim is high. A statement of claim will only be struck out where it is plain and obvious that the pleading should be struck on the basis of one of the grounds detailed in Rule 221(1).

[4] In the case of a Rule 221(1)(a) motion, the Court will only strike a statement of claim where it is plain and obvious that the pleading discloses no reasonable cause of action. In making that assessment, the material facts pleaded must be taken as true, unless the allegations are based on assumption and speculation. If a statement of claim contains bare assertions without material facts upon which to base those assertions, then it discloses no cause of action and is liable to be struck. However, if there is any doubt as to whether a cause of action can succeed, the matter should be left for a decision of the trial judge [see *Operation Dismantle Inc v Canada*, [1985] 1 SCR 441 at paras 7-8, 27; and *R v Imperial Tobacco Canada Ltd*, 2011 SCC 42 at para 17].

[5] On the requirement to plead material facts at the time the claim is commenced, the Supreme Court of Canada stated in *R v Imperial Tobacco Canada Ltd*, *supra* at para 22:

... It is incumbent on the claimant to clearly plead the facts upon which it relies in making its claim. A claimant is not entitled to rely on the possibility that new facts may turn up as the case progresses. The claimant may not be in a position to prove the facts pleaded at the time of the motion. It may only hope to be able to prove them. But plead them it must. The facts pleaded are the firm basis upon which the possibility of success of the claim must be evaluated. If they are not pleaded, the exercise cannot be properly conducted.

[emphasis added.]

[6] A pleading must be read as generously as possible with a view to accommodating any inadequacies in the allegations [*Condon v Canada*, 2015 FCA 159].

[7] Pursuant to Rule 221(2), no evidence is permitted on a motion to strike pursuant to Rule 221(1)(a). Instead, the Court is required to limit its examination to the matters set out in the pleadings. In that regard, the Court may generally consider not only the formal pleadings but also the particulars provided by a party in response to a demand for particulars, as particulars furnished in an action form part of the pleadings [*Bosum v Canada*, 2004 FC 842 at para 7].

[8] As has been recognized by the Federal Court of Appeal, it is fundamental to the trial process that a plaintiff plead material facts in sufficient detail to support the claim and relief sought. Pleadings play an important role in providing notice and defining the issues to be tried. The Court and opposing parties cannot be left to speculate as to how the facts might be variously arranged to support various causes of action [*Mancuso v Canada (Minister of National Health and Welfare)*, 2015 FCA 227 at para 16-17 [*Mancuso*]].

[9] The Federal Court of Appeal recognized at paragraph 17 of *Mancuso* that:

The latter part of this requirement – sufficient material facts – is the foundation of a proper pleading. If a court allowed parties to plead bald allegations of fact, or mere conclusory statements of law, the pleadings would fail to perform their role in identifying the issues. The proper pleading of a statement of claim is necessary for a defendant to prepare a statement of defence. Material facts frame the discovery process and allow counsel to advise their clients, to prepare their case and to map a trial strategy. Importantly, the pleadings establish the parameters of relevancy of evidence at discovery and trial

[emphasis added]

[10] An analysis of the sufficiency of the material facts pleaded in the Statement of Claim is contextual and fact-driven. As stated by the Federal Court of Appeal in *Mancuso*:

There is no bright line between material facts and bald allegations, nor between pleadings of material facts and the prohibition on pleading of evidence. They are points on a continuum, and it is the responsibility of a motions judge, looking at the pleadings as a whole, to ensure that the pleadings define the issues with sufficient precision to make the pre-trial and trial proceedings both manageable and fair.

[11] In assessing the sufficiency of the material facts in a patent infringement action, a statement of claim should clearly show: (a) facts by virtue of which the law recognizes a defined right as belonging to the plaintiff; and (b) facts that constitute an encroachment by the defendant on that defined right of the plaintiff. If a statement of claim does not disclose these two elements of the plaintiff's cause of action, the statement of claim does not disclose a cause of action and may be disposed of summarily [see *Dow Chemical Co v Kayson Plastics & Chemicals Ltd*, (1966), 47 C.P.R. 1 at para. 27 (Can. Ex. Ct) [*Dow Chemical*]].

[12] A defendant is entitled to understand clearly and precisely the exact nature of the invention, as well as how the precise manner in which, according to the plaintiff, the defendant has infringed the claims of the patent [see *Chart Industries Ltd v Hein-Werner of Canada Ltd* (1998), 25 CPR (3d) (Fed TD) para 2].

[13] However, even in circumstances where the pleading is missing some elements and others are incomplete, if the pleading contains enough information to allow the defendant to know with some certainty the case to be met, the pleading will not be struck [see *Pharmaceutical Partners of Canada Inc v Faulding (Canada) Inc*, 2002 FCT 1010 at para 13].

[14] In the case of a Rule 221(1)(c) or (f) motion, a pleading will be struck as being scandalous, frivolous or vexatious or an abuse of process where the claim is so clearly futile that it has not the slightest chance of succeeding [see *Apotex Inc v Syntex Pharmaceuticals International Ltd*, 2005 FC 1310 at para 33].

[15] A pleading may be struck as frivolous or vexatious where the claimant can present no rational argument, based upon the evidence or law, in support of the claim, or where the pleading is so deficient in factual material that the defendant cannot know how to answer and a Court will be unable to regulate the proceeding [see *kisikawpimootewin v Canada*, 2004 FC 1426 at para 8]. A pleading may be struck as an abuse of the Court's process if the action was commenced as a fishing expedition in the hopes that a cause of action will become apparent [see *Kastner v Painblanc*, [1994] FCJ No 1671 at para 4 (FCA)].

[16] In the face of a potentially novel claim, the approach taken by the Court must be generous and err on the side of permitting a novel but arguable claim to proceed to trial [*R v Imperial Tobacco*, 2011 SCC 42].

**(a) Damages or an Accounting of Profits**

[17] Items 1 and 14 of revised Schedule A seek to strike those portions of the Statements of Claim that seek damages and/or an accounting of profits. Sandoz asserts two arguments on this issue: (i) as a matter of law, damages or an accounting of profits are not available remedies under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*Regulations*]; and (ii) no damages or profits can be claimed by the Plaintiffs as Sandoz is not and cannot be in the

market before a Notice of Compliance is issued and no Notice of Compliance can be issued by Health Canada pending the outcome of these actions.

[18] In relation to the first argument, Sandoz asserts that monetary damages or profits are not contemplated in section 55.2 of the *Patent Act*, R.S.C. 1985, c.P-4 [*Act*], nor in the *Regulations*. Rather, the section (1) and 6(4) of the *Regulations* and the nature of the proceedings essentially exclude infringement damages or profits from their scope, as actions brought under the *Regulations* are intended to prevent infringement before it occurs and thus the focus of the Court's inquiry is forward looking – namely, whether or not the second person's product would infringe the asserted claims of the patents in issue. If it would infringe, the Court will grant a remedy preventing the second person from infringing and thus avoiding the occurrence of any damages. While section 6(4) allows the Court to order any other remedy that is available under the *Act*, at law or in equity in respect of infringement, at first instance there will never be any damages or profits to order. Sandoz asserts that the other remedies addressed in section 6(4) are aimed at alternative means of preventing infringement, i.e. injunctive relief, which is supported by the fact that there is no express mention of damages or an accounting of profits in either the *Regulations* or the *Regulatory Impact Analysis Statement*.

[19] Moreover, Sandoz asserts that interpreting the regulatory regime as permitting claims for damages or an accounting of profits would frustrate the regulatory regime as it would be almost impossible to meet the tight timelines prescribed by the *Regulations* if the parties also had to address monetary claims.

[20] In response, the Plaintiffs assert that damages or an accounting of profits are available in section 6(1) actions as the *Regulations* now provide for the full and final determination of all

issues regarding infringement, validity and remedies in respect of patent infringement and by virtue of section 6.01 of the *Regulations*, a first person is required to raise all issues in the section 6(1) action (including claims for damages or an accounting of profits), as the first person is precluded from bringing any future actions when a second person addresses a patent in a Notice of Allegation.

[21] Moreover, the Plaintiffs assert that actions under the *Regulations* no longer seek a declaration prohibiting the issuance of a Notice of Compliance but rather seek a final, binding determination of infringement and validity of a patent. There are now several instances under the *Regulations* that will arise where the second person receives a Notice of Compliance, including: (i) where the first person waives the 24-month stay, meaning the Minister is not precluded from issuing a Notice of Compliance; (ii) where the Court orders, on motion by the second person, that patents are ineligible for listing on the Patent Register, thus no longer triggering the 24-month stay while the action continues; and (iii) where the Court at first instance finds for the second person, a Notice of Compliance is issued and then the Court of first instance is reversed on appeal, resulting in the need for a rehearing.

[22] Neither this Court nor the Federal Court of Appeal has yet to make any determination as to whether or not damages or an accounting of profits are available under the *Regulations*. Given the absence of any case law on this issue and given the broad wording of section 6(4) of the *Regulations* which, on its face, leaves open the possibility that damages or profits are available remedies to a plaintiff in a section 6(1) action, I find that the Plaintiffs' general claim for damages or an accounting of profits is novel and arguable. I therefore decline to exercise my discretion to strike the claim for damages or an accounting of profits on the basis that, at law,



such remedies are not available in a section 6(1) action. However, the Plaintiffs must still have pleaded the necessary material facts in support of their claim for damages or an accounting of profits, which I now turn to in addressing Sandoz's second argument.

[23] In relation to the claim for damages, the Plaintiffs assert that they are entitled to damages based on Sandoz's past and present acts on infringement, which are limited to Sandoz's promotion and marketing of its proposed product in Canada. The Plaintiffs allege that this conduct has resulted in damage to the Plaintiffs and accordingly, their claim for damages is appropriately pleaded. The Plaintiffs acknowledge that the quantum of damages may presently be nominal, but a limited damages claim does not mean that the pleadings fail to disclose a reasonable cause of action.

[24] Sandoz asserts that its past and present promotional and marketing activities (as evidenced by the publications included in the Plaintiffs' motion materials) cannot constitute acts of infringement and in any event, would fall within the regulatory activity exemption in section 55.2 of the *Act*.

[25] I note that it is not the Court's role on a pleadings motion to evaluate Sandoz's promotional and marketing materials included in the motion materials to determine, for example, whether the press release relied upon by the Plaintiffs could demonstrate that Sandoz marketed its proposed product in Canada. This is not a motion for summary judgment. Moreover, on a motion under Rule 221(1)(a), evidence is inadmissible and the Court must determine whether a reasonable cause of action is disclosed based on the pleadings themselves and the particulars previously provided by the Plaintiffs. Having considered the pleadings and the particulars provided by the Plaintiffs, I am satisfied that sufficient material facts have been pleaded in

support of the Plaintiffs' claim to damages based on Sandoz's past and present promotional and marketing activities.

[26] However, I find that the Plaintiffs' pleadings do not disclose a reasonable cause of action vis-à-vis any future claim for damages grounded in the possible issuance of a Notice of Compliance. None of the three scenarios noted above have occurred in this action, such that there is any prospect that a Notice of Compliance will be issued prior to the determination of the actions. First, there has been no waiver of the 24-month stay. Second, there has been no order that any of the patents at issue are ineligible for listing on the Patent Register. Third, there has been no trial and thus no determination on the merits to take to appeal.

[27] The prospect for future damages in this case is entirely hypothetical. Future damages would only arise "if and when" certain events occur in the future. Under the second scenario, Sandoz would have to bring a delisting motion, be successful on the motion, obtain a Notice of Compliance, come to market with its proposed drug product and cause damage to the Plaintiffs as a result thereof. In the third scenario, damages will only ever arise if the Plaintiffs lose at trial, commence an appeal, a Notice of Compliance issues, Sandoz comes to market and then the Plaintiffs are successful on appeal in a manner that would send the matter back for redetermination with the prospect of damages arising on any redetermination. In both scenarios, there is of course also the possibility that the Plaintiffs would obtain injunctive relief to prevent Sandoz from coming to market prior to the determination of the actions, which if granted would eliminate the prospect for any damages.

[28] The Plaintiffs' current pleadings contain no material facts that would support a claim for future damages and the Court cannot condone leaving a hypothetical claim in the pleadings on

the basis that it is effectively a placeholder for “if and when” various events may occur that would ground a claim for damages. I am mindful of the prohibition on future actions contained in section 6.01 of the *Regulations*, but I note that it contains an exception for future actions where the first person or owner of the patent did not, within the 45-day period referred to in section 6(1), have a reasonable basis for bringing an action. A reasonable basis for bringing an action requires that a party be aware of the necessary material facts to underpin a reasonable cause of action. Where those material facts have not yet arisen, the situation would be one that would arguably fall within the exception in section 6.01.

[29] In any event, unless the actions are already determined, there is also the prospect for the Plaintiffs to amend their existing claims if and when new material facts come to light to underpin a claim for future damages. For example, were Sandoz to bring a delisting motion, be successful on the motion and a Notice of Compliance issue to Sandoz prior to the determination of the relevant action, the Plaintiffs could bring a motion to amend their pleadings in the action to assert a further claim for damages.

[30] Moreover, to permit pleadings to stand that seek future damages based on the third scenario advanced by the Plaintiffs would prove entirely unworkable from a procedural and evidentiary perspective. In such a scenario, there would be no evidence to support a claim for future damages at trial and the claim would inevitably be dismissed. Were the Plaintiffs to lose at trial, be successful on other grounds of appeal and the matter is then sent back to the Court for a redetermination, there would still be no evidence before the Court upon which to assess damages. Effectively, an entirely fresh procedure would have to be undertaken to re-plead the

claim for damages, produce relevant documents, conduct discoveries and then call additional evidence at trial. Such a procedure is simply not workable.

[31] Accordingly, the Plaintiffs' claim for damages as currently pleaded shall be limited to the claim for damages incurred as a result of Sandoz's past and present promotional and marketing activities. Any claim related to future damages is hereby struck as disclosing no reasonable cause of action and as constituting an abuse of process. However, the striking of this portion of the pleadings is without prejudice to the right of the Plaintiffs to seek leave to amend should the Plaintiffs become aware of additional material facts that could support a claim for future damages, such as the delisting of any relevant patents and the resulting issuance of a Notice of Compliance.

[32] In relation to the claim for profits, Sandoz asserts that the Plaintiffs have not pleaded that Sandoz has sold its proposed product and to the contrary, the Plaintiffs have admitted that Sandoz has not sold and is not presently selling its proposed product. In the absence of any sales, there can be no profits. I agree with Sandoz. I find that the pleadings disclose no material facts to support a claim for any profits that have arisen to date.

[33] As for the prospect of an entitlement to an accounting of profits based on future profits, I note that the submissions made by the Plaintiffs in their written representations and at the hearing focused primarily on the issue of damages. No distinct submissions were made on the issue of profits. For the same reasons noted above in relation to future damages, I find that the claim for an accounting of profits shall be struck as disclosing no reasonable cause of action and as constituting an abuse of process. However, the striking of this portion of the pleadings is

without prejudice to the right of the Plaintiffs to seek leave to amend should the Plaintiffs become aware of additional material facts that could support a claim for an accounting of profits.

**(b) Past and Present Conduct**

[34] In light of my findings under the sub-heading of damages or an accounting of profits, I need not separately determine those items in revised Schedule A relating to Sandoz's past and present promotional and marketing activities.

**(c) Section 55.2**

[35] Items 2 through 6, 8, 8.1, 11 and 13 of revised Schedule A seek to strike various paragraphs of the Statements of Claim on the basis that the pleadings conflict with the exemption in section 55.2 of the *Act*. Section 55.2(1) of the *Act* provides:

It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

[36] Sandoz relies on this Court's decision in *Purdue Pharma v Collegium Pharmaceutica, Inc*, 2018 FC 199 [*Purdue*], where the Honourable Mr. Justice O'Reilly held at paragraph 20 that a statement of claim will be deficient on its face where it merely alleges activities that would fall within the statutory exemption in section 55.2. Sandoz asserts that the Plaintiffs' pleadings improperly asserts that the followings acts undertaken by Sandoz in the development and submission of information to Health Canada and provincial formularies constitute acts of infringement:

- A. Sandoz made, constructed and manufactured, or had made, constructed and manufactured for its benefit, Sandoz's proposed product;
- B. Sandoz filed a submission for a Notice of Compliance from Health Canada;
- C. Sandoz represented to Health Canada that its proposed product is a biosimilar drug to Rituxan;
- D. Sandoz advertised and marketed its proposed product to be used in place of Rituxan; and
- E. Sandoz will apply to formularies to obtain listing and reimbursement for its proposed product for use in place of, instead of and for the same uses as Rituxan.

[37] The Plaintiffs argue that in considering this issue, the scope of the *Regulations* should not be interpreted based on the prior case law, as section 55.2(4) of the *Act* was amended in September 2017 such that the *Regulations* are no longer limited to the prevention of infringement of a patent. The current wording of section 55.2(4), under which the recent amendments to the *Regulations* were made, reads:

The Governor in Council may make regulations respecting the infringement of any patent that, directly or indirectly, could result or results from the making, construction, use or sale of a patented invention in accordance with subsection (1), including regulations

...

(f) respecting the resolution of disputes with respect to the infringement of a patent that results directly or indirectly from the manufacture, construction, use or sale of such a product;

(g) conferring rights of action with respect to disputes referred to in any of paragraphs (d) to (f). [emphasis added]

[38] The Plaintiffs assert that the preclusion effect of section 6.01 of the *Regulations* and the legislature's desire to have a full and final determination of the issues of infringement and validity warrant all issues being decided together in these proceedings, including those now being disputed by Sandoz in this category.

[39] The Plaintiffs point to the language of section 6(1) of the *Regulations* in support of the propriety of their pleading, which section provides:

The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.

[40] The Plaintiffs assert that the act of filing a New Drug Submission with Health Canada is the basis for the right of action under section 6(1) and in and of itself, is the basis for the issuance of a declaration of infringement. The Plaintiffs assert that the language of section 6(1) of the *Regulations*, coupled with the revised language of section 55.2(4) of the *Act*, support an assertion that the filing of a New Drug Submission can be an act of infringement, notwithstanding the language of section 55.2 of the *Act*.

[41] Moreover, the Plaintiffs assert that Sandoz has to plead as a defence that its acts of infringement fall within section 55.2 of the *Act* (which it has done) and then must prove so at trial. The Plaintiffs plead in their Reply and Defence to Counterclaim in each action that the acts of infringement do not all constitute conduct that would fall within the exemption in section 55.2

and the Plaintiffs assert that there is no obligation on their part to expressly plead that the acts of infringement are for non-regulatory purposes.

[42] I will begin my analysis with a consideration of the case law under the prior version of the *Regulations*. The Federal Court of Appeal held in *Apotex Inc v Allergan, Inc*, [2011] FCJ No 580 at para 4 [*Apotex*], that the mere fact that a defendant pharmaceutical company had sought regulatory approval to market a medicine did not by itself support an action for patent infringement. On a motion to strike, the Court must pay careful attention to the precise pleading before the Court to determine whether the pleading alleges sufficient material facts beyond generalities and conclusions of infringement and alleges facts that fall beyond the scope of regulatory activity.

[43] Without something pleaded beyond the regulatory requirements, section 55.2 of the *Act* applies and the pleading is liable to being struck [*Purdue, supra*; and *Eli Lilly Canada Inc v Nu-Pharm Inc*, [2011] FCJ No 419 [*Eli Lilly*]; *Apotex, supra*].

[44] In the aforementioned cases, the parties had not expressly pleaded that the delivery of the New Drug Submission was, in and of itself, an act of infringement. In *AstraZeneca Canada Inc v Novopharm Ltd*, [2010] FCJ No. 526 [*Astra Zeneca*], the Federal Court of Appeal stated that such an allegation would be novel and would have to be specifically pleaded in order for the court to address it. The Honourable Madam Justice Snider confirmed in *Eli Lilly* that a specific pleading that an Amended New Drug Submission, a Notice of Compliance and a DIN constitute acts of infringement may be a sufficient basis for allowing an infringement action to proceed.



[45] I find that, as recognized in *Astra Zeneca* and *Eli Lilly*, the allegation that Sandoz's filing for a Notice of Compliance is an infringing act is a novel and arguable claim. In light of the recent amendments to the *Regulations* and the fact that this issue has not yet been addressed by this Court or the Federal Court of Appeal, I will exercise my discretion to permit this claim to proceed to trial.

[46] At the hearing of the motion, the Plaintiffs argued that their allegation that Sandoz had made, constructed and manufactured their proposed product did not relate solely to activities that would come within the section 55.2 exemption, as their allegation was not limited to regulatory activities. Put differently, the Plaintiffs assert that Sandoz has made, constructed and manufactured their proposed product for non-regulatory purposes. This is consistent with the Plaintiffs' Reply and Defence to Counterclaim in each action. However, I find that insufficient material facts have been pleaded in relation to this allegation of the nature described by the Federal Court of Appeal in *Apotex, supra*.

[47] Accordingly, I find that paragraph 35.1 of the proposed Amended Statement of Claim in T-823-18 and the related paragraphs in the proposed Amended Statements of Claim in the related actions must be further amended to provide particulars of the non-regulatory activities allegedly undertaken by Sandoz.

[48] With respect to the documents enumerated in item 3 (namely, the documents contained in the dossier associated with the relevant new drug submissions), I see no basis to strike this portion of the pleadings. The pleading that the documents and materials contained in the dossier are relevant to the action is a statement of law, not fact. Nothing is served by striking this sentence. Moreover, simply pleading that such documents and materials are relevant does not

render them producible or the basis for permissible examination for discovery. The Plaintiffs will still have to establish the relevance of any and all such documents as the case moves forward.

[49] While the disputed paragraphs in this category also included allegations that Sandoz has advertised and marketed its proposed product in Canada, I did not receive any submissions from Sandoz that those portions of the pleadings should be struck on the basis of the activities falling within the regulatory activity exemption in section 55.2 and as such, I see no basis to strike those portions of the pleadings.

[50] With respect to item 13, I am not satisfied that Sandoz has established that it is plain and obvious that the pleading discloses no reasonable cause of action vis-à-vis submissions to be made by the Plaintiffs to formularies on the basis that such activity is covered by the regulatory exemption in section 55.2. As there is a dispute between the parties as to the scope of activity that falls within section 55.2, I find that that is matter for determination at trial.

[51] In light of my findings above, I see no basis to strike any of the other disputed paragraphs of the pleadings in this category.

**(d) Acting in Concert**

[52] In relation to item 8 on revised Schedule A, Sandoz seeks to strike from the Statements of Claim the allegation that Sandoz will act “in concert” with others, namely formularies and hospitals, to infringe the asserted claims of the various patents at issue as set out in paragraph 34 of the Statement of Claim in T-832-18, paragraph 38 of the Statement of Claim in T-824-18, paragraph 36 of the Statement of Claim in T-825-18 and paragraph 46 of the Statement of Claim in T-826-18.

[53] Sandoz originally asserted that the claims were improper as they amounted to a claim of conspiracy that was missing the necessary material facts. However, the Plaintiffs asserted in their responding materials that Sandoz had mischaracterized their pleadings as they are not asserting conspiracy. Rather, the Plaintiffs are asserting a claim for patent infringement involving Sandoz's activities with formularies and hospitals that can be characterized as contributory infringement or acting in concert. In that regard, the Plaintiffs rely on the decision of this Court in *Bauer Hockey Corp v Easton Sports Canada Inc*, 2010 FC 361 [*Bauer*], where the Honourable Madame Justice Gauthier stated:

[205] This case is very different and can be easily distinguished from all those referred to by Easton's counsel. This has nothing to do with one party procuring or inducing another to use a combination by procuring one component of the combination. Here, through Mr. Laferrière's involvement (as well later as that of Mr. Daniel Chartrand), Easton was actually participating in the making of the skates that are now found to infringe.

[206] As such, while it is not necessary to come to a conclusion in the case at bar, it is worth mentioning for future consideration that in England the courts applied the concept of infringement "by common design", a notion that also exists in Canada although it has not been applied in the context of a patent infringement action. In *Unilever plc v. Gillette (UK) Limited*, [1989] R.P.C. 583 (U.K.C.A.), at p. 609, Lord Mustill, then at the Court of Appeal of England, noted:

I use the words "common design" because they are readily to hand, but there are other expressions in the cases, such as "concerted action" or "agreed on common action" which will serve just as well. The words are not to be construed as if they formed part of a statute. They all convey the same idea. This idea does not, as it seems to me, call for any finding that the secondary party has explicitly mapped out a plan with the primary offender. Their tacit agreement will be sufficient. Nor, as it seems to me, is there any need for a common design to infringe. It is enough if the parties combine to secure the

doing of acts which in the event prove to be infringements.

[54] The Plaintiffs argue that their plea of acting in concert is in keeping with the description of the cause of action in *Bauer* and that sufficient material facts have been pleaded to support the allegation.

[55] Sandoz asserts that the claim properly amounts to a claim of contributory infringement, which has been expressly rejected as a reasonable cause of action under Canadian law in *Apotex Inc v Nycomed Canada Inc*, 2011 FC 1441 at para 21 (and affirmed on appeal, 2012 FCA 195), as an allegation of contributory infringement cannot meet the second prong of the inducement test. To the extent that the Plaintiffs now assert that the cause of action is “acting in concert” or “by common design”, Sandoz asserts that such a cause of action has never been recognized in the context of a patent infringement action.

[56] While the concept of infringement by common design has not been applied in the context of a patent infringement action, this Court has recognized its existence under Canadian law [see *Bauer, supra*]. I find that the Plaintiffs’ use of the phrase “acting in concert” would fall within the concept of infringement by common design, as conceptually they are no different. Although the Plaintiffs’ allegation may be novel, I find that the claim is at least arguable and therefore should not be struck on this basis.

[57] However, I am not satisfied that the Plaintiffs have provided the necessary particulars related to this specific allegation. As this cause of action is novel, it is all the more important that the necessary particulars related to the allegation are pleaded. Moreover, as this action is governed by the *Regulations*, the need for the necessary particulars is heightened, as the parties

must “hit the ground running” and adhere to the Court’s tight timelines for moving the actions forward. Allegations of this nature cannot wait for further particularization or exploration on discovery.

[58] While the pleadings contain material facts related to Sandoz’s dealings with hospitals and formularies, the Plaintiffs have not provided any particulars of the conduct of the hospitals and formularies - how they are specifically acting in concert with Sandoz, the nature of their tacit agreement or plan, and whether there is any alleged intention on the part of the hospitals and formularies to infringe the asserted claims of the various patents. Moreover, the Plaintiffs’ responding motion materials suggest that the category of third parties alleged to be acting in concert with Sandoz may not be restricted to hospitals and formularies as currently pleaded. The Plaintiffs must therefore provide particulars of all third parties whom they assert are acting in concert with Sandoz and cannot leave the pleading open ended in this regard.

[59] Accordingly, the Plaintiffs’ claims of acting in concert are struck, with leave to amend to plead the particulars noted above.

**(e) Request for Particulars**

[60] To be successful on a motion for particulars, the moving party must establish that: (a) the information sought is necessary or material particulars; (b) the particulars are not within the moving party’s knowledge or that the opposing party has no cause to assume that they are within the knowledge of the moving party; and (c) the particulars are necessary to enable the moving party to plead in response to the impugned pleadings [see *Tyhy v Schulte Industries Ltd*, 2004 FC 1421 at para 9].

[61] To establish that the requested particulars are necessary for pleading and not within its knowledge, a moving party's affidavit in support of a motion for particulars must, in general, contain details as to what information is needed for pleading and why the moving party, without such information, would be unable to instruct counsel for the purposes of replying to the pleading [see *Styker Corp v. Umano Medical Inc*, 2016 FC 378 at para 27; *Abercrombie & Fitch Co v Giant Tiger Stores Limited*, 2009 FC 492 at para 11]. However, where the need for particulars is clear on the face of the pleading, affidavit evidence to establish the need for particulars is not required [see *Chen v Canada (Minister of Citizenship and Immigration)*, 2006 FC 389].

[62] In relation to items 3, 4, 7, 8 and 9 of revised Schedule B, Sandoz asserts that: (i) the Plaintiffs have failed to provide the necessary material facts to support their claim of infringement such that Sandoz does not understand how their proposed product is alleged to infringe the asserted claims of the Plaintiffs' various patents; and (ii) the Plaintiffs have provided only bald denials of Sandoz's claims of invalidity which fail to address fundamental issues such as claims construction and the identification of the notional skilled person. Sandoz asserts that these defects in the pleadings are curable and requests that the Court order the Plaintiffs to provide the particulars in relation to these items, failing which the relevant portions of the pleadings should be struck.

[63] In response, the Plaintiffs assert that Sandoz's failure to put forward an affidavit in response to its request for particulars to demonstrate that it truly cannot understand the Plaintiffs' claims and position is fatal to its request for particulars, as no deficiency is evident from the face of the Plaintiffs' pleadings. Moreover, the Plaintiffs assert that: (i) Sandoz seeks particulars

going to expert evidence and construction of the terms of the patent, which are improper; and (ii) Sandoz improperly seeks to reverse the burden on validity and does not seek material facts, but rather improperly seeks evidence, expert opinion, legal conclusions and claims construction.

[64] In relation to item 3, Sandoz asserts that in the Statements of Claim in T-823-18, T-825-18 and T-826-18 only, the pleadings fail to provide particulars of the purported connection between the words of the product monograph and the assertions made so as to understand how it is alleged that Sandoz's proposed product infringes the asserted claims of the various patents. Having reviewed the pleadings in their entirety, I am satisfied that sufficient material facts have been pleaded so as to permit Sandoz to understand the claim being asserted by the Plaintiffs and in the absence of any affidavit evidence from Sandoz in relation to this item, I see no basis to order the requested particulars.

[65] In relation to item 4, Sandoz asserts that the Plaintiffs have failed to plead their position as to the "benefits" or "invention" of the patents and therefore any tie between the patents and the acts of Sandoz. Again, having reviewed the pleadings in their entirety, I am not satisfied that there is any defect on the face of the pleadings. Given the absence of any affidavit evidence from Sandoz in relation to this item, I am not prepared to exercise my discretion to order the requested particulars. Moreover, it is difficult to accept Sandoz's suggestion that it unaware of the benefits of rituximab for the uses at issue when Sandoz has developed its own biosimilar for the claimed uses.

[66] In relation to items 7, 8 and 9, these items all relate to denials made by the Plaintiffs in their Reply and Defence to Counterclaim of various allegations of invalidity and defences to infringement made by Sandoz and as such are traverses, in respect of which no particulars are

required. Moreover, given the absence of affidavit evidence in support of the request for particulars, I am not satisfied Sandoz needs these particulars to properly move forward with the proceeding.

**THIS COURT ORDERS that:**

1. The Plaintiffs' claim for future damages in this action and related actions T-824-18, T-825-18 and T-826-18 is struck, without prejudice to the right of the Plaintiffs to seek leave to amend should the Plaintiffs become aware of additional material facts that could support a claim for future damages.
2. The Plaintiffs' claim for an accounting of profits in this action and related actions T-824-18, T-825-18 and T-826-18 is struck, without prejudice to the right of the Plaintiffs to seek leave to amend should the Plaintiffs become aware of additional material facts that could support a claim for an accounting of profits.
3. The Plaintiffs' claim of acting in concert in this action and related actions T-824-18, T-825-18 and T-826-18 is struck, with leave to amend to plead the particulars detailed in paragraph 6.
4. The balance of the Defendant's motions to strike is dismissed.
5. The Defendants' motions for particulars are dismissed in their entirety.
6. The Plaintiffs are granted leave to serve and file their Amended Statement of Claim and Amended Reply and Defence to Counterclaim in the forms provided in their responding



motion records in relation to each of T-823-18, T-824-18, T-825-18 and T-826-18, subject to:

- a. The claim for future damages being removed therefrom;
  - b. The claim for an accounting of profits being removed therefrom;
  - c. Further amendments to plead the material facts related to the Defendant's making, constructing and manufacturing a rituximab product which it says is equivalent to Rituxan in a manner that would fall outside the scope of section 55.2 of the *Patent Act*; and
  - d. Further amendments to plead the material facts as to the specific third parties with whom the Defendant is acting in concert, how those third parties are acting in concert with the Defendant, the nature of the Defendant's tacit agreement or plan with those third parties and whether there is any alleged intention on the part of those third parties to infringe the asserted claims of the various patents.
7. The Plaintiffs shall serve and file their amended pleadings in each action by no later than November 14, 2018.
  8. In light of the divided success on the motions, there shall be no costs of the motions.
  9. A copy of this Order shall be placed in related actions T-824-18, T-825-18 and T-826-18.

  
Case Management Judge